



DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent License: Oligonucleotides Analogues

Targeting Human LMNA “lamin A” Gene

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Human Genome Research Institute (NHGRI), an institute of the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an Exclusive, Sublicensable Patent License to consolidate co-owned rights to the inventions and the Patents and Patent Applications listed in the Supplementary Information section of this notice to The Progeria Research Foundation (“PRF”), having a place of business in 200 Lake Street, Unit 102. Peabody, MA 01960.

DATES: Only written comments and/or applications for a license that are received by the NHGRI Office of Technology Transfer Office on or before **[INSERT DATE 15 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]** will be considered.

ADDRESSES: Requests for a copy of the patent application(s), inquiries, and comments relating to the contemplated license should be directed to: Eggerton Campbell, License and Patent Manager, NHGRI Technology Transfer Office, Telephone: 301-402-1648; email: eggerton.campbell@nih.gov.

SUPPLEMENTARY INFORMATION:

The following and all continuing U.S. and foreign patents/patent applications thereof are the intellectual properties to be licensed under the prospective agreement:

Country	Title	Application No.	Patent No.
United States	Methods For Treating Progeroid Laminopathies Using Oligonucleotide Analogues Targeting Human LMNA NIH E-044-2013-0-US-01	61/568,590	
WIPO	Methods For Treating Progeroid Laminopathies Using Oligonucleotide Analogues Targeting Human LMNA NIH E-044-2013-0-PCT-03	PCT/US12/068609 WO 2013/086444	
United Kingdom	Methods For Treating Progeroid Laminopathies Using Oligonucleotide Analogues Targeting Human LMNA NIH E-044-2013-0-GB-12	12806796.4	2788488
United States	Methods For Treating Progeroid Laminopathies Using Oligonucleotide Analogues Targeting Human LMNA NIH E-044-2013-0-US-02	13/708,709	9,326,992
United States	Methods For Treating Progeroid Laminopathies Using Oligonucleotide Analogues Targeting Human LMNA NIH E-044-2013-0-US-06	15/084,255	9,833,468
United States	Methods For Treating Progeroid Laminopathies Using Oligonucleotide Analogues Targeting Human LMNA NIH E-044-2013-0-US-07	15/727,483 CON	10,398,721
Europe	Methods For Treating Progeroid Laminopathies Using Oligonucleotide Analogues Targeting Human LMNA NIH E-044-2013-0-EP-04	12806796.4	2788488
Japan	Methods For Treating Progeroid Laminopathies Using Oligonucleotide Analogues Targeting Human LMNA NIH E-044-2013-0-JP-15	2019-109410	
France	Methods For Treating Progeroid Laminopathies Using Oligonucleotide Analogues Targeting Human LMNA NIH E-044-2013-0-FR-11	12806796.4	2788488
Germany	Methods For Treating Progeroid Laminopathies Using Oligonucleotide Analogues Targeting Human LMNA NIH E-044-2013-0-DE-10	12806796.4	2788488

Ireland	Methods For Treating Progeroid Laminopathies Using Oligonucleotide Analogues Targeting Human LMNA NIH E-044-2013-0-IE-13	12806796.4	2788488
Japan	Methods For Treating Progeroid Laminopathies Using Oligonucleotide Analogues Targeting Human LMNA NIH E-044-2013-0-JP-05	2014-546152	6132849
Japan	Methods For Treating Progeroid Laminopathies Using Oligonucleotide Analogues Targeting Human LMNA NIH E-044-2013-0-JP-08	2017-41744	
Netherlands	Methods For Treating Progeroid Laminopathies Using Oligonucleotide Analogues Targeting Human LMNA NIH E-044-2013-0-NL-14	12806796.4	2788488
Switzerland	Methods For Treating Progeroid Laminopathies Using Oligonucleotide Analogues Targeting Human LMNA NIH E-044-2013-0-CH-09	12806796.4	2788488
United States	Oligonucleotide Analogues Targeting Human LMNA NIH E-044-2013-1-US-01	62/330,027	
WIPO	Oligonucleotide Analogues Targeting Human LMNA NIH E-044-2013-1-PCT-02	PCT/US17/30174 WO 2017/190041	
United States	Oligonucleotide Analogues Targeting Human LMNA NIH E-044-2013-1-US-16	16/096,524 (371-national phase)	10,822,608
United States	Oligonucleotide Analogues Targeting Human LMNA	17/024,100	
Australia	Oligonucleotide Analogues Targeting Human LMNA NIH E-044-2013-1-AU-03	2017258642	
Brazil	Oligonucleotide Analogues Targeting Human LMNA NIH E-044-2013-1-BR-04	BR1120180722790	
Canada	Oligonucleotide Analogues Targeting Human LMNA NIH E-044-2013-1-CA-05	3,022,303	
China	Oligonucleotide Analogues Targeting Human LMNA NIH E-044-2013-1-CN-06	201780040785.7	
Colombia	Oligonucleotide Analogues Targeting Human LMNA NIH E-044-2013-1-CO-07	NC2018/0012783	

Eurasia	Oligonucleotide Analogues Targeting Human LMNA NIH E-044-2013-1-EA-08	201892467	
Europe	Oligonucleotide Analogues Targeting Human LMNA NIH E-044-2013-1-EP-09	17735676.3	
Hong Kong	Methods For Treating Progeroid Laminopathies Using Oligonucleotide Analogues Targeting Human LMNA NIH E-044-2013-1-HK-17	19126894.5	
India	Oligonucleotide Analogues Targeting Human LMNA NIH E-044-2013-1-IN-10	201847043433	
Japan	Oligonucleotide Analogues Targeting Human LMNA NIH E-044-2013-1-JP-11	2019-508165	
Korea (South)	Oligonucleotide Analogues Targeting Human LMNA NIH E-044-2013-1-KR-12	10-2018-7034615	
Mexico	Oligonucleotide Analogues Targeting Human LMNA NIH E-044-2013-1-MX-13	MX/A/2018/013157	
New Zealand	Oligonucleotide Analogues Targeting Human LMNA NIH E-044-2013-1-NZ-14	747685	
Singapore	Oligonucleotide Analogues Targeting Human LMNA NIH E-044-2013-1-SG-15	11201809468X	

The patent rights in these inventions have been assigned to the Government of the United States of America, the University of Maryland, Sarepta Therapeutics, Inc, and the Progeria Research Foundation (PRF), co-owners of said rights, for commercial development and marketing. The rights to be granted by NHGRI are controlled by NHGRI by virtue of co-ownership and a license received to the listed intellectual property. The prospective patent license will be for the purpose of consolidating the patent rights to PRF. Consolidation of these co-owned rights is intended to expedite development of the invention, consistent with the goals of the Bayh-Dole Act codified as 35 U.S.C. 200-212. The prospective patent license will be worldwide, exclusive, may be

limited to those fields of use commensurate in scope with the patent rights, and will be sublicensable.

The subject technology pertains to modified oligonucleotides (called phosphorodiamidate morpholino oligonucleotides or PMOs) targeted to pre-mRNA of human LMNA Lamin A gene. These PMOs can be used to correct aberrant splicing of LMNA gene known to be involved in Hutchinson-Gilford Progeria Syndrome (HGPS), and could be used in treating this ultra-rare disease and related laminopathies.

This notice is made in accordance with 35 U.S.C. 209 and 37 CFR part 404. The prospective Exclusive Patent License will be royalty bearing and may be granted unless, within fifteen (15) days from the date of this published notice, the NHGRI Technology Transfer Office receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR part 404.

Complete applications for a license that are timely filed in response to this notice will be treated as objections to this to the grant of the contemplated exclusive patent license.

In response to this Notice, the public may file comments or objections. Comments and objections, other than those in the form of a license application, will not be treated confidentially, and may be made publicly available.

License applications submitted in response to this Notice will be presumed to contain business confidential information and any release of information from these license applications will be made only as required and upon a request under the *Freedom of Information Act*, 5 U.S.C. 552.

Dated: June 29, 2021

Claire T. Driscoll,

Director,

Technology Transfer Office,

National Human Genome Research Institute,

National Institutes of Health.

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